REMARKS

Claims 1 to 15 are under consideration. Claim 1, 11 and 13-15 (and dependent claims there from) have been amended. Reconsideration of all claims 1 to 15 is requested.

FIRST, Applicant is resubmitting a copy of the Interview Record submitted on October 16, 2006.

SECOND, Applicant is also submitting a Declaration Under 37 C.F.R 1.132 by Applicant Rashida A. Karmali.

THIRD, since Examiner Handy has not responded fully to Applicant's Response of 21 July 2006, but summarily repeated the main points of last Office Action dated March 23, 2006, Applicant is resubmitting the Response filed 21 July 2006, below. Pursuant to MPEP 707.07(f) "If a rejection of record is to be applied to a new or amended claim, specific identification of that ground of rejection, as by citation of the paragraph in the former office letter in which the rejection was originally stated, should be given." The Examiner should provide support for his conclusions as a matter of law and fact. That is the Examination Standard set forth in different sections of MPEP 707, whether or not the Examiner has the time to do so.

FOURTH, Examiner Handy has ignored the discussion held during the interview on October 15, 2006, when he explicity stated that Applicant had overcome the rejections based on Schramm and Nason, but that Examiner Handy was not convinced that Liotta was overcome. See Applicant's Interview Summary.

In the interview, Applicant pointed out that the capillary tube in the present invention was not comparable to Liotta's capillary pipette, and that the main utility of the present invention was to provide a device that collected adequate small amounts of blood or other specimens and prevent waste of biological samples. Applicant reiterated the argument made in the July 21, 2006 response that the present invention meets an unmet need- to provide a device to collect small amounts of biological specimens and prevent waste. Examiner Handy's response was that he had to meet the deadline to issue an Office Action immediately and did not have time to review the specification. And indeed, he issued a Final Office Action without any regard to his obligations to provide proper examination and not piecemeal examination. MPEP 707 (g).

Relevant sections of July 21, 2006 Response Reproduced below

Claim Rejections- 35 USC "§ 103

Claims 1-15 were rejected as being unpatentable over Schramm et al. (5,935,864) in view of Nàson (4,978,504) and further in view of Liotta et al. (5,942,407).

Page 3, lines 3-12: The Action states "*Schramm teaches a method and kit for collecting samples of liquid specimens for analytical testing. The device is best shown in Figures 2, 4 and 5. The device includes a sample container (5) with an open top (9) and lower capillary end (4), an immunoassay test strip (12) and a vial containing reagents and/or buffers and sealed with a penetrable foil. The lower end of the container has an inwardly extending portion (6) that forms an air-tight seal with the vial. Figures 3-5 show how the device is used. The process is described in column 4, lines 15-42. Capillary volume capacity is given in column 3, lines 29-31. Schramm does not teach a filter in the container, does not cite specific materials of construction, does not teach colorimetric analysis and does not teach a coated capillary*".

In response, applicant agrees with the Action, that Schramm on its own is distinguishable from the present invention because it lacks the following four elements:

- 1) a filter in the container
- 2) does not describe the materials of construction
- 3) does not teach colorimetric analysis, and
- 4) does not teach a coated capillary.

Page 3, line14 to page 4, line 6: "*Nason teaches a specimen test unit the test unit is best shown in Figures 12-15. The device includes to (14) and bottom caps ((60) containing a*

swab sampling element (20) in a housing (30). The housing includes a filter for filtering samples and reagents that flow into the housing and to the collection (bottom) vial. The housing is made of plastic to accommodate deformation (column 5, lines 58-62). Nason discloses colorimetric analysis on reaction products in a vial in column 9, lines 19-25 and column 10, lines 20-25. It would have been obvious to one of ordinary skill in the art to combine the cited features from Nason with the device of Schramm. One would use plastic in order to provide a deformable, yet resilient body structure. One would add the caps to seal the body structure. One would add the filters in order to filter mixed components, trap components and/or provide additional reagents as suggested by Nason (column 8, lines 5-15). One would perform colorimetric analysis on the contents of the test device in order to safeguard the operator from contact with samples and reagents (col. 9, lines 24-31). The combined teachings of Scramm and Nason do not teach a coated capillary."

In response, applicant agrees in part and disagrees in part. In col. 5, lines 58-62, Nason describes that the housing is made of plastic. However, applicant is not arguing that this is the distinguishing feature because this is not a unique feature in the present invention.

Similarly, in col. 9, lines 19-25, Nason describes that the vial 70 is placed in a colorimetric device to measure the color change. However, applicant is not arguing that colorimetric measure of color change is unique in this invention. The color change in applicant's invention is recorded more easily, i.e., visually and does not require a device.

Moreover, the filter members 18 and 19 are serially mounted and filter 19 terminates in a rounded contour, col. 8, lines 5-15. Col 9, lines 24-31, cited in the Action, describe optical detection in a device without requiring the vial to be touched. These features are NOT present in the present invention and in fact distinguish it from Nason.

Applicant agrees with the Action that the combination of Schramm and Nason still does not teach the most unique feature of the invention – the coated capillary tube that is part

of the collection device. In other words, there is no support to reject claims 1-15 based on Schramm in view of Nason. And this rejection should be withdrawn.

Page 4, lines 7- 16: *"Liotta et al. teaches an immunoassay device for determining analytes in a test sample. In discussing the signal-generating zone of the device, Liotta notes that it would be advantageous if the sample did not have any calcium present so it would be preferable to chelate the calcium with chelating agents. Liotta then goes on to state that the chelating agents could be added during dilution steps, incorporated into a sample collection device or coated onto a capillary pipette (column 12, lines 46-67). It would have been obvious to one of ordinary skill in the art to provide the chelating agent as a coating on the capillary. Schramm and Nason include an immunoassay device. One would add the chelating agents to the input capillary of Schramm and Nason in order to remove materials that would interfere with the immunoassay."*

In response, applicant disagrees because the cited section specifically states that "Specifically, an EDTA vacutainer or an EDTA coated capillary pipette could be utilized."

The present invention does not contain an EDTA vacutainer or EDTA coated capillary pipette. It contains a "chamber having a support means at the distal end and a filter membrane at the proximal end, wherein the capillary tube is volumetrically graduated and internally coated with an agent including a buffer, anticoagulant, detergent, stabilizer or a preservative". Therefore, as a matter of fact, there is no basis for Liotta to be relevant prior art. Moreover, Liotta employs aequorin as the photoprotein and requires a luminometer device for sensing light. These elements are NOT present in the present invention. There is no basis to support the rejection of claims 1-15 based on Schramm in view of Nason in view of Liotta. The rejection should be withdrawn.

Page 4, lines17-21: *"As for the graduated markings on the capillary, it would have been obvious to one of ordinary skill in the art to add markings for volume. Claim 12 recites a plurality of containers having color-coded identifiers. Providing a plurality of containers to perform a number of different tests would be obvious to one of ordinary skill in the art. More containers would allow for more tests."*

In response, applicant agrees, because there are no available plurality of containers having color-coded identifiers on the market. This means that hospitals have to use individually wrapped

containers. This is expensive and inefficient—in other words, there is a need for more cost effective and convenient availability of specimen collecting devices packages together. Therefore, under Graham v. John Deere, Co 383 U.S. 1, 148 USPQ 459 (1966), this rejection should be withdrawn because the invention meets a current need and will reduce cost.

LEGAL STANDARD

As a matter of law, the above rejection under 35 USC §103 cannot be sustained. The Federal Circuit, has held that:

"The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention." Hodosh v. Block Drug Co., Inc., 786 F.2d 1136, 1143 n.5, 1986 MPEP 2141.

"To make a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure." In re Vaeck 947 F. 2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) (MPEP §2143 and 2142).

" When the motivation to combine the teachings of the references is not immediately apparent, it is the duty of the examiner to explain why the combination of the teachings is proper". Ex parte Skinner, 2 USPQ 1788 (Bd. Pat. App. & Inter. 1986).

In this regard, there is no teaching or suggestion whatsoever in Schramm/Nason/Liotta of improving a specimen collecting and analytical assembly by combining a) a one piece barrel container having an open top and a capillary tube with an open end, with a chamber disposed there between, b) the chamber having a support means at the distal end and a filter membrane at the proximal end, wherein the capillary tube is volumetrically graduated and internally coated with an agent including a buffer, anticoagulant, detergent, stabilizer or a preservative, and, c) wherein the top of the barrel houses a vial containing a suitable reagent therein.

Therefore, as a matter of fact and law, there is no basis to sustain the rejections of any of the claims under consideration 1 through 15 as being obvious over Schramm in view of Nason and Liotta. This rejection should be withdrawn.

End of July 21, 2006 Response

The Final Action issued 10/19/2006

Response to Arguments

The Action states: "Applicant's arguments filed 7/21/06 have been fully considered but they are not persuasive. The previous rejection may be summarized as follows; Schramm teaches every element of the claims except for the materials, filter, colored reagents, and coated capillary. Nason provides a teaching of plastic materials, a filter and colored reagents. Liotta provides a coated capillary.

Applicant has argued that the addition of Liotta to the combined teachings of Schramm and Nason is not proper since Liotta is not relevant prior art (page 3, lines 14-23 of the submitted Arguments). Applicant has also argued that hindsight would be required for one of ordinary skill in the art (interview 10/16/06). The Examiner respectfully disagrees on both counts. The combined teachings of Schramm and Nason teach a collection device that collects a sample and reacts with a reagent to form a product. The product may then be analyzed by visual or optical means to determine the contents of the sample. Liotta also teaches the analysis of a sample by colorimetric or optical assay. Applicant has argued that Liotta does not, in fact, disclose the coated capillary. The Examiner disagrees. Liotta recites that a coated vaccutainer or coated capillary pipette could be utilized in collecting the sample (column 12, lines 46-67).(emphasis added)

In response, applicant strongly disagrees. By the Examiner's own admission, Liotta recites a coated vaccutainer or coated capillary pipette. Both these devices are different and distinguishable from the capillary tube of the present invention. In fact, coated vaccutainers have been known in the art for a long time, and the vaccutainer tubes are especially pressurized to draw blood by suction. And pipettes that are coated have been used to draw samples by suction (mouth or rubber tip). However, there is no teaching in the art for capillary tubes being coated with anything and then used for drawing biological samples. This is because a very clean inside surface of the capillary tube is

required to create a capillary force for the specimen to be drawn by this capillary force up the tube, and usually in very small volumes. See Paragraph # 2(h), Declaration of Rashida Karmali.

As indicated by Dr Karmali it was after several attempts that the coating of the capillary tube was achieved such that it did not interfere with the drawing of the specimen or block the opening of the capillary tube. See Paragraph # 2(i) to (j), Declaration of Rashida Karmali.

As indicated by Dr. Karmali, one skilled in the art associates a capillary glass tube with the short thin glass tube which is open at both ends. This is used to collect blood, then one end is plugged by heating, and the tube is centrifuged to obtain the hematocrit. See Paragraph # 2(k), Declaration of Rashida Karmali.

Therefore, there is no support for the above rejection and it should be withdrawn.

The Final Action further states:

Schramm and Nason teach colorimetric analysis of a sample collected through a capillary end portion (element 4 of Scramm). Liotta teaches the colorimetric analysis of a collected sample and in addition teaches that the sample may be collected through a sample collection device having a capillary element coated with a material that both stabilizes the sample and removes interefering metal cations through the use of chelating agents (column 12, lines 46-67). The Examiner submits that this is indeed relevant to the combined teachings of Scramm and Nason and that no hindsight is required. Liotta clearly recites the use of a coated capillary [pipette] in collecting the sample. Schramm and Nason teach a collection device that collects a sample through a capillary element (40 and then analyzes the sample by visual or optical means. The addition of the coated element from Liotta prevents metal ions in the sample from interfering with the optical analysis in Liotta. (emphasis added) The Examiner submits this would be recognized by one of ordinary skill in the art as being an advantageous addition to the teachings of Scramm and Liotta. Adding the reagents to the inside of the entrance [of] capillary [pipette] would provide a stable sample that is free of interfering metal ions. (emphasis added)

In response, applicant wants to remind the examiner that his reliance on Liotta is misplaced, because the present invention in no way deals with interference caused by chelating metals. As pointed out by Dr. Karmali, one skilled in the art would not find it advantageous to use Liotta's teachings on method of activating light emission by a photoprotein adapted for use in a diagnostic assay and providing a substrate having a coated or impregnated with a dried salt of a metal cation and a dried caged metal cation compound

to produce a dried metal cation zone.....Claim 1 of Liotta. The mere fact that Liotta mentions the word "capillary" does not make it relevant art. See Declaration, #(h) to (k).

Therefore, there is no basis to sustain the above rejections. In any event, applicant has amended claims 1, 11 and 13-15 to include the novelty characteristic of designed to draw up to 2000 μl of sample. Applicant urges the examiners to devote appropriate time to review this case and seriously consider the case law to sustain an obviousness rejection and not base their conclusions just because they say so- as examiners. That is not the Examination standard required by the MPEP.

Notice to the effect that claims 1-15 are allowable is respectfully requested.

Respectfully submitted,

Rashida A. Karmali

Date: December 18, 2006

Rashida A. Karmali, Esq.
Reg. No. 43,705
Attorney for Applicant
99 Wall Street 13th Floor
New York, New York 10005
Tel: (212) 651-9653
Fax: (212) 651-9654